December 18, 2019

Ethicon, Inc
Eleanor Zhou
Regulatory Affairs Specialist
Route 22 West, P.O. Box 151
Somerville, New Jersey 00876-0151

Re: K192580
Trade/Device Name: STRATAFIX Spiral Monocryl, Plus Bidirectional Knotless Tissue Control Device
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 18, 2019
Received: September 19, 2019

Dear Eleanor Zhou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192580

Device Name
STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device

Indications for Use *(Describe)*
STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submitter: Ethicon Inc. a *Johnson & Johnson* company
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510(k) Number: K192580

Date Prepared: December 16, 2019

Device Trade Name: STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device

Device Common Name: Suture, Surgical, Absorbable, Polyglcolic Acid

Class: II

Classification Name: Suture, Absorbable, Synthetic, Polyglcolic Acid (21 CFR 878.4493)

Product Code: GAM

Predicate Device	510(k) Number
STRATAFIX™ Spiral MONOCRYL™ *Plus* Knotless Tissue Control Device (Primary)	K182873
Quill™ Self-Retaining System (SRS) comprised of MONODERM™ (Additional)	K072028

Device Description:

The STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device is an antibacterial monofilament, synthetic absorbable device prepared from a copolymer of glycolide and ε-caprolactone. The device contains IRGACARE®* MP (triclosan), a broad spectrum antibacterial agent, at no more than 2360 μg/m. The device is available in a dyed and undyed version. The pigment for the dyed version is D&C Violet No. 2. Poliglecaprone 25 copolymer has been found to be nonpyrogenic and elicits only a slight tissue reaction during absorption.

The STRATAFIX™ Spiral MONOCRYL™ *Plus* Knotless Tissue Control Bidirectional Device Design consists of barbed suture material, armed with a surgical needle on each end. The device also contains an unbarbed center transition zone that facilitates the initiation of the device use. The STRATAFIX™ Spiral MONOCRYL™ *Plus* Device barbs allow for tissue approximation without the need to tie surgical knots.

While the formation of barbs in the STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Device reduces the tensile strength relative to non-barbed suture material of the same size, tying of knots in non-barbed suture materials also reduces their effective strength. For this reason, the strength of the STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Device can be compared to USP knot strength of non-barbed sutures. The actual diameter of the non-barbed section fiber is one size greater than the designated size with a maximum overage of 0.1 mm.

The USP and EU Pharmacopoeia sizes of the STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Device are further defined in Table 1.

Table 1. Diameter Comparison

USP DEVICE SIZE DESIGNATION	EU PHARMACOPOEIA DEVICE SIZE (Metric / Ph. Eur.) DESIGNATION	STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional	
		USP	Metric / Ph. Eur.
0	3.5	0	3.5
2-0	3	2-0	3
3-0	2	3-0	2
4-0	1.5	4-0	1.5

TENSILE STRENGTH

STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Device straight tensile strength meets the knot tensile strength for a USP and EU Pharmacopoeia poliglecaprone 25 device of the equivalent size as shown in Table 2.

Table 2. Tensile Strength Comparison

USP DEVICE SIZE DESIGNATION	EU PHARMACOPOEIA DEVICE SIZE (Metric / Ph. Eur.) DESIGNATION	Device Minimum Knot Tensile Strength	
		USP (kgf)	Metric / Ph. Eur. (N)
0	3.5	3.90	39.0
2-0	3	2.68	26.3
3-0	2	1.77	17.4
4-0	1.5	0.95	9.32

Indications for Use:

STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device is indicated for use in soft tissue approximation where the use of absorbable sutures is appropriate.

Performance Data:

Non-clinical laboratory performance testing was performed demonstrating that STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device conforms to the current USP Monograph for absorbable surgical sutures, except for diameter. The testing was performed in accordance with FDA's Guidance Document: "Class II Special Controls Guidance Document: Surgical Sutures" issued on June 3, 2003. Bench testing evaluated: Suture Diameter, Needle Attachment Strength, Tensile Strength, In Vitro Breaking Strength, and Ex Vivo Wound Closure Strength.

Summary of Technological Characteristics and Performance Testing:

The STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device has similar technological characteristics as the predicate devices. Like the currently marketed predicate devices, STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device is a sterile, monofilament synthetic absorbable suture intended for the approximation of soft tissue that conforms to the USP Monograph for absorbable surgical sutures, except for diameter. The STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device consists of barbed suture material, armed with a surgical needle on each end. The barbs in STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Device allow the tissue approximation without the need to tie surgical knots.

STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device will be available as a suture product with IRGACARE ®* MP, an antibacterial agent same as STRATAFIX™ Spiral MONOCRYL™ *Plus* Unidirectional predicate device.

Substantial Equivalence:

STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device has the same intended use and indication for use as the predicate devices. The technological differences between the subject device - STRATAFIX™ Spiral MONOCRYL™ Plus Bidirectional Knotless Tissue Control Device and the predicate devices raise no new questions of safety or effectiveness. STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device meets all testing criteria to demonstrate substantial equivalence to the predicates devices.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing STRATAFIX™ Spiral MONOCRYL™ *Plus* Bidirectional Knotless Tissue Control Device has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate devices.